

REMARKS

The sole independent claim presently before the Examiner is new claim 8. New claim 8 specifically recites the conditions of C18-HPLC and the dosage administration of 0.01 to 20 grams.

The present invention is directed to the discovery that the attachment of *Haemophilus influenzae* to human cells can be overcome through the administration of certain components of an aqueous extract of *Pogostemon cablin* and/or *Agastache rugosa*. None of the prior art suggests or discloses such a discovery.

Claim Objections

The Examiner has objected to claims 1-3 because the full Latin name of the microorganism was not presented. It is believed that new claim 8, which uses the full Latin name, *Haemophilus influenzae*, has overcome this rejection.

Claim Rejections 35 USC §112

The Examiner has rejected claims 1-5 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

It is believed that new claim 8, which clearly recites the HPLC conditions is now so informative with respect to the material intended, that one skilled in the art would readily be able to isolate and concentrate same. The recitation of solvents, rates of flow and the like will allow one of ordinary skill to identify and use the components of *Pogostemon cablin* and/or *Agastache rugosa* that are effective in inhibiting the attachment of *H influenzae* to human cells.

In similar fashion, the new independent claim recites a therapeutically effective amount of 0.01 to 20 grams of the respective components. In light of new claim 8, it is

believed that the Examiner's rejection of claims 1-5 under 35 USC §112 has been overcome.

Patent Drawings

Applicant is aware of the Draftperson's objection under 37 CFR 1.84 or 1.152 for Figures 1A through 4B. Once allowable subject matter has been determined, Applicant will submit new drawings.

Double Patenting

The Examiner has rejected claims 1-5 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,776,462. Once allowable subject matter has been determined, Applicant will submit a terminal disclaimer.

Claim Rejections 35 USC §102

The Examiner's rejection of claims 1 and 4 under 35 USC §102(b) as being anticipated by CN1078399 (Reference "O") is traversed.

Reference O cannot anticipate the presently claimed invention since the reference does not comprise administering an identical composition to that presently claimed. Reference O discloses and claims a health tonic containing ingredients camphor, menthol, clove and essential oil, characterized in that it contains an ethanol extract of the following crude drug ingredients: sandalwood, clove, *Agastache rugosa*, and the like. Reference O further discloses a health drug that can have various bodily functions such as stimulating the mind and restoring consciousness, relieving all kinds of fatigue, and restoring physical strength and energy. There is no disclosure or teaching of inhibiting the attachment of *H. influenzae* cells to human cells. Further, this reference

makes no suggestion or disclosure that particular components of the aqueous extract would be particularly effective in inhibiting *H. influenzae* attachment to human cells.

Applicant's aqueous extract and its specific components does not alleviate nasal obstruction. Further, there is no alleviation of dizziness reported in the present invention. The aqueous extract and its specific components alleviate the pain and effusion from ear infections such as *Otitis media*. There is simply no teaching or disclosure in Reference O that components derived from an aqueous extract of *Agastache rugosa* would inhibit attachment of *H. influenzae* and/or treating/preventing *Otitis media*.

The Examiner's rejection of claims 1, 2 and 4 under 35 USC 102(b) as being anticipated by JP08176002 (Reference "P") is traversed. Reference P discloses the cell adhesion suppressing effect of various plant extracts using cancer models. Reference P cannot anticipate the present invention since it teaches that the extraction is conducted on all or part of the plant with water or an organic solvent. The organic solvents are numerous as are the recited plant forms.

Reference P also fails to anticipate the present invention since it fails to make any suggestion that *H. influenzae* cells can be inhibited from attaching to human cells through the administration of certain components aqueously extracted from *Agastache rugosa*. The Examiner has failed to cite any reference which would lead one to believe that cancerous cell attachment inhibition would be predictive of *H. influenzae* attachment inhibition. Any reading of Reference P would not lead one skilled in the art to predict that certain components of *Agastache rugosa* would inhibit the attachment of *H. influenzae* cells. For these reasons, Reference P cannot be considered to anticipate the claimed invention since the compositions are different and there is no suggestion in Reference P relating to *H. influenzae* and/or treating/preventing *Otitis media*.

The present invention does not associate a treatment or prevention of *Otitis media* with the treatment of cold symptoms, which is the distress of the upper respiratory tract that the Examiner recites. The Examiner has inappropriately stretched the teachings of Reference P beyond what one skilled in the art would consider scientifically justified.

Claim Rejections 35 USC §103

The Examiner's rejection of claims 1, 2 and 4 under 35 USC §103(a) as being unpatentable over Reference O and Reference P taken with CN1078399 (Reference "N") is traversed. As discussed above, References O and P are insufficient to anticipate the present invention and further, their combination does nothing to overcome their shortcomings recited above.

It is believed that the Examiner has cited CN1078399 as both Reference O and Reference N. Applicant is confused and believes that Reference N is meant to be CN1063796. Reference CN1063796 discloses a tea for treatment of alcohol intoxication. The tea is prepared by grinding a mixture of chrysanthemum, cudsu flowers, Chinese hawthorne, *Agastache rugosa* and tea leaves. There is no disclosure nor suggestion of inhibiting the attachment of *H. influenzae* to human cells as a method of treating or preventing *Otitis media*. Further, there is no suggestion that three (3) specific components derived from *Agastache rugosa* would be effective in treating or preventing *Otitis media*. There is no reasonable expectation of treating disorders relating to cell attachment including attachment of *H. influenzae* and/or in treating/preventing distresses associated with *Otitis media* in CN1063796.

The present invention does not suggest or disclose that its composition would be effective for nasal obstructions. The Examiner has inappropriately extended the teachings of References O, P and N in an attempt to make out a *prima facie* case of

obviousness. The Examiner has failed to consider new claim 8, which recites specific peaks and dosages for the inhibition of *H. influenzae* attachment. The Examiner has failed to correctly tie these references together to make out what the present Applicant has contributed to the state of the art.

It is respectfully submitted that the §103 rejection, based on the combination of References O, P, and N has been overcome.

Conclusion

Applicant believes that the claims presently before the Examiner are distinguishable from the prior art cited and applied by the Examiner. It is submitted that the claims are in a condition for allowance and allowance is respectfully solicited.

Should the Examiner have any questions or concerns prior to passing this case onto allowance, she is requested to contact Applicant's undersigned representative.

Respectfully submitted,

By: Donald O. Nickey Oct 21, 2003
Donald O. Nickey, Reg. No. 29,092
Attorney for Applicant
8765 Colvin Drive
Plain City, Ohio 43064
Phone: (614) 757-5542
Fax: (614) 757-2243